

# EXHIBIT B

**EXHIBIT B TO GENERAL TVT RETROPUBIC  
EXPERT REPORT OF NICOLE B. FLEISCHMANN, MD**

**(Updated March 22, 2016)**

**List of Materials Reviewed by Nicole Fleischmann, MD**

**Company Documents:**

1. 1998 TVT Professional Education Program Speaker's Guide Slide Deck [ETH.MESH.05795537-99]
2. 2001 Slides from Paul Parisi binder - Gynecare TVT Tension-free Support for Incontinence Professional Education Slides [ETH.MESH.05795421-508]
3. 2002 Dr. Miklos Presentation Slides Minimizing & Managing Intraoperative Complications: TVT Sling [ETH.MESH.00397674]
4. 2002 TVT Advanced Users Forum Presentation Slides: Gynecare TVT Tension-free Support for Incontinence [ETH.MESH.08156958]
5. 2003 - Gynecare TVT: Tension-free Support for Incontinence General Professional Education Presentation Slides [ETH.MESH.00373310-88]
6. 2006 - TVT-O Summit Presentation Slides by Raders and Lucente [ETH.MESH.00993273]
7. 2007 Pelvic Floor Summit Agenda [ETH.MESH. 02109874-75]
8. 2008 Pelvic Floor Summit Agenda [ETH.MESH. 00819498-99]
9. 2008 - Treatment of SUI with the Gynecare TVT Family of Products Presentation Slides [ETH.MESH.00369995]
10. 2008.12.10 TVT Patient Brochure
11. 2009 - The Science of 'What's Left Behind...' Evidence & Follow-Up of Mesh Use for SUI by Dr. Doug Grier [ETH.MESH.03751819]
12. 2010 - Gynecare TVT Exact Professional Education Presentation Slides [ETH.MESH.00295355]
13. 2012 - Gynecare TVT Exact Continence System Professional Education Presentation Slides-Updated [ETH.MESH.08117473]

14. 2013 - Clinical Expertise Tension-free Midurethral Sling: Market Update Presentation Slides-Prof Ed [ETH.MESH.10281860]
15. 2015 TVT IFU
16. 2015 TVT Patient Brochure
17. TVT 'Stop Coping...' Patient Brochure – [ETH.MESH.06087471-72]
18. Gynecare TVT...SUI affects 1 in 3 women... Patient Brochure – [ETH.MESH.06087513-14]
19. 'Stop Coping...' Gynecare TVT Patient Brochure – [ETH.MESH.08003295-302]
20. 'Stop Coping...' Gynecare TVT Patient Brochure – [ETH.MESH.08003303-18]
21. Corbet-IFU- 17-In Use From 11/29/10 to Present [ETH.MESH.03427878-946]
22. Gynecare TVT Tension-free Support for Incontinence Advanced Users Forum for the Experienced Clinician Presentation Slides [ETH.MESH.10220659]
23. Gynecare TVT Tension-free Support for Incontinence Professional Education Presentation Slides [ETH.MESH.08107354]
24. The History of TVT [ETH.MESH.03932912-914]
25. TVT IFU In Use From 10/13/08 to 11/22/10 [ETH.MESH.2340504-567]
26. TVT IFU In Use From 11/29/10 to Present [ETH.MESH.3427878-946]
27. TVT IFU 2008 [ETH.MESH.05222687]
28. 01/28/98 Letter from FDA re: K974098 TVT System [ETH.MESH.371496-594]
29. 11/11/10 Letter from John Young re: Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 1) [ETH.MESH.341006-11]
30. Patient Brochure: "Stop coping, start living." [ETH.MESH.8003303-17]
31. Patient Brochure: "Stop coping, start living." [ETH.MESH.8003295-301]
32. Surgeon's Resource Monograph, A Report of the June 2000 Summit Meeting [ETH.MESH.658177-658198]
33. TVT Surgeons Resource Monograph - June 2000 [ETH.MESH.10027307-28]
34. TVT Surgeons Resource Monograph copy review form [ETH.MESH.00161387-89]

35. Clinical Evaluation Report, Gynecare TVT Tension-free Vaginal Tape / Tension-free Vaginal Tape Accessory Abdominal Guide [ETH.MESH.4384126-65]
36. 09/07/2009 Safety review: TVT and TVT-O procedures [ETH.MESH.1751069-94]
37. Clinical Expert Report [ETH.MESH.1784823-28]
38. Email re: Performance Evaluation of TVT Prolene Blue Mesh [ETH.MESH.6696411-19]
39. Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT
40. Letter to Weisberg/Robinson re: Elongation Characteristics of Laser Cut PROLENE Mesh for TVT, from Kammerer [ETH.MESH.1222075-79]
41. Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2
42. Email from Seppa re: Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)
43. Memo from Kammerer/ Silimkhan re: Ultrasonic Slitting of PROLENE Mesh for TVT [ETH.MESH.04949544-567]
44. Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006 [ETH.MESH.00308599-606]
45. Risk Management Report, TVT Laser Cut Mesh (LCM). Document Number RMR-0000017, Rev. 3 [ETH.MESH.223779-84]
46. Email re: Mesh Fraying Dr. EBERHARD letter [ETH.MESH.7692905-7]
47. Memo re: VOC on new Laser Cut TVT Mesh [ETH.MESH.6878438-39]
48. Email re: Important Laser cut mesh update [ETH.MESH.1809056-58]
49. Memo re: Comparison of Laser-cut and machine-cut TVT Mesh to Meshes from Competitive Devices (BE02004-1641) [ETH.MESH.1809080-81]
50. Email re: TVT Laser Mesh info [ETH.MESH.442825-26] PowerPoint Mechanical vs. "Machine"-cut Mesh, January 19, 2005 Prepared by: Allison London Brown & Gene Kammerer
51. Email re: Laser Cut TVT [ETH.MESH.6859834-35]
52. Email re: TVT Meeting with Agency [ETH.MESH.524746-48]
53. Email re: TVT Laser Cut Mesh [ETH.MESH.525573]

54. Memo re: TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis [ETH.MESH.1784779-82]
55. Email re: OR Agenda Tunn [ETH.MESH.3922926-28]
56. KOL Interview [ETH.MESH.4048515-20]
57. Gynecare TVT Tension-free Support for Incontinence: Professional Education Slides
58. Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician[ETH.MESH.08156958]
59. 05/13/2003 Memo to Gynecare Continence Health Sales Team re: Gynecare TVT Physician Training Policy [ETH.MESH.7393700]
60. Application FMEA for TVT Classic Doc# FMEA-0000536 Rev.<1>
61. Final Report, PSE Accession No. 97-0197, Project No. 16672 [ETH.MESH.5315252-65]
62. 10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture
63. Spreadsheet of TVT & TVT-O RCTs to 11-2012 [ETH.MESH.08307644-45]
64. TVTO PA (TOPA) RD Memo on PA Mesh Assessments for TVT-O PA – Katrin Elbert [ETH.MESH.09922570]
65. Tension-Free Vaginal Obturator Tape (TVOT) – April 30, 2003 – Meeting Report [ETH.MESH.3934952-67]
66. Clinical Expert Report [ETH.MESH.222899-909]
67. Email from Arnaud re Transient Leg Pain with Mulberry [ETH.MESH.3911390-1]
68. Email from Dan Smith re Draft report translated by “Babel fish” <http://babelfish.altavista.com>tr [ETH.MESH.865069-72]
69. Email from Dan Smith re NG TVT-O NDP – Outcomes from Kickoff Meeting with Pr. De Leval & Dr. Waltregny [ETH.MESH.2293715-6]
70. Email from Hinoul re South Africa, TVTO sheaths getting stuck upon removal [ETH.MESH.1210987-95]
71. Email from O’Bryan re GYNECARE TVT Obturator System – FDA [ETH.MESH.6882641-2]
72. Email from O’Bryan re ifu [ETH.MESH.3364663-66]
73. Email from Weisberg re IFU update [ETH.MESH.3365250-1]

74. Email from Weisberg re Mulberry [ETH.MESH.6886410-11]
75. Gynecare Final Report # 030740, TVT Obturator System 12-15-03 [ETH.MESH.222852-63]
76. Gynecare TVT Obturator System Sales Materials [ETH.MESH.161953-54]
77. History of TVT-O [ETH.MESH.3932909-11]
78. Manuscript Draft (de Leval) Novel surgical technique for the treatment of female SUI Transobturator Vaginal Tape [ETH.MESH.262089-123]
79. Project Mulberry, Preliminary Clinical Diligence Report [ETH.MESH.1815660-64]
80. Transobturator Vaginal Tape Inside-Out (TVT-O) From Development to Clinical Experience [ETH.MESH.823793-806]
81. TVT O IFU [ETH.MESH.2340902-8]
82. TVT-O Key Steps Guide [ETH.MESH.03416986]
83. TVT Obturator Brochure; “Results, Precision & Proven Mesh” [ETH.MESH.2236604-09]
84. TVT Abbrevio IFU
85. PowerPoint, “EWH&U Professional Education” by Lissette Caro Rosado [ETH.MESH.00803652-78]
86. SOP Regulatory Labeling Guidance HMESH\_ETH\_11642462
87. LNE Pore Size Test [ETH.MESH.02211890]

**Publicly Sourced Documents:**

1. ACOG - (FAQ081) Frequently Asked Questions in Urinary Incontinence
2. ACOG (1995) technical bulletin: Urinary Incontinence. No. 213 - Oct. 1995 (Replaces No. 100, Jan. 1987)
3. ACOG (2005) Practice Bulletin 63 Clinical Management Guidelines for Obstetrician-Gynecologists - Urinary Incontinence in Women
4. ACOG AUGS Joint Position Statement on Uncomplicated SUI-CO 603 (June 2014)
5. ACOG Patient Information Sheet (FAQ166) - Frequently Asked Questions in Surgery for Stress Urinary Incontinence (2011)
6. ACOG Practice Bulletin Number 155 November 2015 (Replaces Practice Bulliten 63, June 2005)
7. ACOG Practice Bulletin Summary Number 155 November 2015 (Replaces Practice Bulliten 63, June 2005)
8. ACOG (2011) Committee Opinion Number 498 August 2011 Adult Manifestations of Childhood Sexual Abuse
9. AUA - SUI Monograph (2011)
10. AUA 2011 Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary
11. AUA 2013 SUI Patient Guide
12. AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of SUI (2013)
13. AUA SUI Pocket Guide for Physicians
14. AUA/SUFU Guideline Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults 2012|Amended 2014
15. AUA: American Urological Association Education and Research. Guideline for the surgical management of female stress urinary incontinence: 2009 Update. Linthicum (MD): American Urological Association Education and Research, Inc.: 2009. 44p.
16. AUA: American Urological Association Education and Research. Guideline for the surgical management of female stress urinary incontinence: 2009 Update Appendices A11 & A16. 2012 Revision

17. AUGS 2013 Position Statement on Restrictions of Surgical Options for Pelvic Floor Disorders
18. AUGS Committee Opinion 603 Evaluation of Uncomplicated SUI in Women Before Surgical Treatment
19. AUGS SUFU Patient FAQs MUS for SUI 2014 Mar 12
20. AUGS SUFU Provider FAQs MUS for SUI 2014 Mar 12
21. AUGS-SUFU MUS Position Statement on Mesh Midurethral Slings for SUI, Jan 3, 2014
22. British Association of Urological Surgeons - BAUS - Synthetic Vaginal Tapes for Stress Incontinence, Dec 2012
23. EAU - TVT-O for the treatment of female stress
24. EAU 2012 Guidelines on Surgical Treatment of Urinary Incontinence - 3.4. Midurethral slings
25. FDA Labeling Device Guidance/Blue Book Memo
26. FDA Executive Summary: Surgical Mesh for Treatment of Women With Pelvic Organ Prolapse & Stress Urinary Incontinence: Obstetrics & Gynecology Devices Advisory Committee Meeting Sept. 8-9, 2011
27. FDA Position Statement re Considerations about Surgical Mesh for SUI, March 27, 2013
28. FDA Presentation - FDA Perspectives on Surgical Mesh for Stress Urinary Incontinence (SUI) - Sept 9, 2010 Pressley
29. FDA Public Health Notification - 2008 Oct. 20
30. FDA Public Health Notification - 2011 July 11
31. FDA's May 2014 Response to Public Citizen
32. ICS Factsheets 2013 Edition - SUI - p 13 2<sup>nd</sup> paragraph regarding use of the midurethral sling as the treatment of choice
33. ICS/IUGA 2011 graft complications standard definitions (<http://www.ics.org/complication>)
34. IUGA (2011) - Stress Urinary Incontinence: A Guide for Women
35. IUGA (July 2014) Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence



36. IUGA Position Statement on MUS
37. NICE 2013 Sept Clinical Guideline 171- Urinary incontinence: The management of urinary incontinence in women
38. Oxford Levels of Evidence Pyramid for Practitioners
39. Premarin Advertisement
40. SUFU 2015 February Winter Meeting Abstracts

**Medical Literature:**

1. Abbott S, et al (2014) Evaluation & management of complications from synthetic mesh after reconstructive surgery: A multicenter study. *Am J Obstet Gynecol* 2014; 201:163e-1-8
2. Abdel-Fattah, Randomized trial-3 year followup-ICS Meeting. *Neurourol Urodyn* 2011.
3. Abdelmonem (2010) Vaginal length & incidence of dyspareunia after total abdominal vs vaginal hysterectomy. *European Journal of Obstetrics & Gynecology and Reproductive Biology*. 151 (2010) 190-192
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5. Abramov, Y, et al. Site-specific rectocele repair compared with standard posterior colporrhaphy. *Obstet Gynecol*. 2005 Feb; 105(2):314-8.
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7. Aigmueller, Ten-year follow-up after the tension-free vaginal tape procedure. *American Journal of Obstetrics & Gynecology* 2011.
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10. Amat Tardiu, Contasure-Needleless compared with transobturator-TVT for the treatment of stress urinary incontinence. *Int Urogynecol J* 2011: 827-833.
11. Amid (2004) Ch. 19 Shrinkage - Fake or Fact In Meshes - Benefits and Risks
12. Amid, PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. *Hernia* (1997) 1: 15-21
13. Angioli, Tension-free vaginal tape versus transobturator suburethral tape-5 year follow up Results of a Prospective, Randomised Trial. *Eur Urol* 2010: 671-677.
14. Araco, TVT-O vs TVT. A randomized trial in patients with different degrees of urinary stress incontinence. *Int Urogynecol J* 2008: 917-926.

15. Athanasiou et al (2014) Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail? *Int Urogynecol J* (2014) 25:219-225 [Pop 124, 7 yr fu]
16. Athanasiou, Mixed Urodynamic Incontinence: TVT or TVT-O .[Pop 75]. *Int Urogynecol J* 2009; 20; Suppl 2; Abs 173.
17. Atmaca et al (2008) Time Dependent Changes in Biomechanical Properties of Four Different Synthetic Materials in a Rabbit Model and the Importance in Respect to Sling Surgery. *Urol Int* 2008; 81:456-461
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24. Blaivas et al (2013) Salvage surgery after failed treatment of synthetic mesh sling complications *J Urology.* Volume 190, Issue 4, pgs 1281-1286. Oct 2013
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33. Canel et al (2015) Postoperative groin pain and success rates following transobturator midurethral sling placement: TVT Abbrevio system v TVT Obturator system. *Int Urogyn J*, 2015 Oct; 26(10)1509-16
34. Capobianco et al (2014) TVT Abbrevio: efficacy and two years follow up for the treatment of stress urinary incontinence. *Clin Exp Obst & Gyn*
35. Cheng & Liu (2012) Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five year follow up. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 161 161 (2012) 228-231
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46. de Leval et al (2007) in French: Actualites Therapeutiques en Urologie Le TVT-O, nouvelle technique mini invasive pour le traitement de l'incontinence urinaire d'effort feminine, developpements et experience clinique *Rev Med Liege* 62: Synthese 2007: 86-94
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**Expert Reports:**

1. Blaivas, Jerry
2. Ducheyne, Paul
3. Elliot, Daniel (& materials cited in footnotes of Mullins expert report)
4. Iakovlev, Vladimir
5. Jordi, Howard
6. Kenton, Kimberly
7. Klinge, Uwe
8. Muehl, Thomas
9. Pence, Peggy
10. Rosenzweig, Bruce (& materials cited in footnotes of Mullins expert report)
11. Tolia, Marc

**Deposition Transcripts & Exhibits:**

1. Blaivas, Jerry
2. Elliot, Daniel
3. Iakovlev, Dr. Vladimir
4. Nager, Charles
5. Rosenzweig, Bruce
6. Tolia, Marc

I have also reviewed all materials or articles cited in my expert report, or supplements thereto, which are not included in this Exhibit B.